

# Research Supplements to Promote Diversity in Health-Related Research

**PA Number:** PA-05-015

## Part I Overview Information

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### Department of Health and Human Services

#### Participating Organizations

National Institutes of Health (NIH), (<http://www.nih.gov>)

#### Components of Participating Organizations

All NIH Institutes and Centers Participate in this Program

#### Announcement Type

This program announcement supersedes and replaces the RESEARCH SUPPLEMENTS FOR UNDERREPRESENTED MINORITIES at <http://grants1.nih.gov/grants/guide/pa-files/PA-01-079.html> and RESEARCH SUPPLEMENTS FOR INDIVIDUALS WITH DISABILITIES at <http://grants1.nih.gov/grants/guide/pa-files/PA-01-080.html>, which were previously issued on April 9, 2001.? And also EXTENDING THE EXPIRATION DATE OF PA-01-079, RESEARCH SUPPLEMENTS FOR? UNDERREPRESENTED MINORITIES AND PA-01-080, RESEARCH SUPPLEMENTS FOR? INDIVIDUALS WITH DISABILITIES <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-04-048.html>.

#### Catalog of Federal Domestic Assistance Number(s)

93.213, 93.393, 93.394, 93.395, 93.396, 93.397, 93.399, 93.389, 93.306, 93.333, 93.371, 93.867, 93.371, 93.867, 93.172, 93.233, 93.837, 93.286, 93.838, 93.839, 93.866, 93.8911, 93.273, 93.855, 93.856, 93.846, 93.2386, 93.209 93.865, 93.279, 93.173, 93.121, 93.847, 93.848, 93.849, 93.1113, 93.114, 93.115, 93.142, 93.309, 93.821, 93.960, 93.880, 93.859, 93.362, 93.375, 93.242, 93.853, 93.361, 93.879, 93.390

#### Key Dates

Release Date: November 19, 2004

Letters Of Intent Receipt Date(s): Not Required

Application Receipt Date(s): Applications can be received at any time

Peer Review Date(s): Applications can be reviewed at any time

Council Review Date(s) : Not applicable

Earliest Anticipated Start Date: Within six months of the receipt of the application

Additional Information To Be Available Date: Notification approximately 10 weeks after receipt

Expiration Date: September 30, 2007

#### Due Dates for E.O. 12372

Not Applicable

#### Executive Summary

The NIH hereby notifies Principal Investigators holding specific types of NIH research grants (listed in the full announcement) that funds are available for administrative supplements to improve the diversity of the research workforce by supporting and recruiting students, postdoctorates, and eligible investigators from groups that have been shown to be underrepresented. Although the administrative supplements supported under this program provide funding for less than one percent of all individuals involved in NIH supported research, the NIH has found these awards to be an effective means of encouraging institutions to recruit from currently underrepresented groups. Administrative supplements must support work within the scope of the original project.

All NIH awarding components participate in this program. Candidates eligible for support under this supplement program include individuals at various career levels who come from groups that have been shown to be underrepresented in science. Such candidates include individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds. Detailed eligibility criteria are described in the full announcement.

The NIH recognizes a unique and compelling need to promote diversity in the biomedical, behavioral, clinical and social sciences research workforce. The NIH expects efforts to diversify the workforce to lead to the recruitment of the most talented researchers from all groups; to improve the quality of the educational and training environment; to balance and broaden the perspective in setting research priorities; to improve the ability to recruit subjects from diverse backgrounds into clinical research protocols; and to improve the Nation's capacity to address and eliminate health disparities.

You may submit (an) application(s) if you are the Principal Investigator, at a domestic institution, who holds an active R01, R10, R18, R22, R24, R35, R37, R43, R44, R41, R42, P01, P20, P30, P40, P41, P50, P51, P60, U01, U10, U19, U41, U42, U54, or S06 grant. Because policies may vary among awarding components regarding eligibility of Small Grant Awards (R03), Academic Research Enhancement Awards (R15), or Exploratory/Developmental Grants (R21) for supplements under this program, **grantees holding those awards must check with the appropriate awarding component before submitting an application for a supplement.**

#### Eligible institutions include:

- For-profit organizations
- Non-profit organizations;
- Public or private institutions, such as universities, colleges, hospitals, and laboratories;
- Units of State government;
- Units of? local government;
- Eligible agencies of the Federal government;
- Domestic institutions/organizations; and
- Faith-based or community-based organizations.

A currently funded Principal Investigator can submit one application on one topic. The application material is available at? <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. An application for a supplement may be submitted at any time. In making requests, the grantee institution, on behalf of the Principal Investigator of the parent grant and in cooperation with the candidate **must submit the application for supplemental funds directly to the awarding component that supports the parent grant . The application must not be submitted to the NIH Center for Scientific Review.**

Telecommunications for the hearing impaired:? TTY 301-451-0088.

There is no setaside amount for this program. The NIH expects to make more than 1,000 administrative supplements under this program at a total cost exceeding \$60 million. Direct costs for individual administrative supplements vary from less than \$5,000 to more than \$75,000 depending on the career level of the candidate (see [Section III.3.](#), below). Requests for administrative supplements can be submitted to the NIH Program Official listed in the contacts section at any time. Administrative supplements normally end with the competitive cycle of the parent grant.

## Table of Contents

### [Part I Overview Information](#)

### [Part II Full Text of Announcement](#)

#### ? [Section I. Funding Opportunity Description](#)

??? 1. Research Objectives

#### ? [Section II. Award Information](#)

??? 1. Mechanism(s) of Support

??? 2. Funds Available

#### ? [Section III. Eligibility Information](#)

??? 1. Eligible Applicants

????? A. Eligible Institutions

????? B. Eligible Individuals

??? 2. Cost Sharing  
??? 3. Other - Special Eligibility Criteria

? [Section IV. Application and Submission Information](#)

??? 1. Address to Request Application Information  
??? 2. Content and Form of Application Submission  
??? 3. Submission Dates  
????? A. Receipt and Review and Anticipated Start Dates  
??????? 1. Letter of Intent  
????? B. Sending an Application to the NIH  
????? C. Application Processing  
??? 4. Intergovernmental Review  
??? 5. Funding Restrictions  
??? 6. Other Submission Requirements

? [Section V. Application Review Information](#)

??? 1. Criteria  
??? 2. Review and Selection Process  
??? 3. Merit Review Criteria  
????? A. Additional Review Criteria  
????? B. Additional Review Considerations  
????? C. Sharing Research Data  
????? D. Sharing Research Resources

? [Section VI. Award Administration Information](#)

??? 1. Award Notices  
??? 2. Administrative Requirements  
????? A. Cooperative Agreement Terms and Conditions of Award  
????? ?? 1. Principal Investigator Rights and Responsibilities  
????? ?? 2. NIH Responsibilities  
????? ?? 3. Collaborative Responsibilities  
????? ?? 4. Arbitration Process  
??? 3. Award Criteria  
??? 4. Reporting

? [Section VII. Agency Contact\(s\)](#)

??? 1. Scientific/Research Contact(s)  
??? 2. Peer Review Contact(s)  
??? 3. Financial/ Grants Management Contact(s)

? [Section VIII. Other Information - Required Federal Citations](#)

## Part II - Full Text of Announcement

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### Section I. Funding Opportunity Description

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#### 1. Research Objectives

The NIH hereby notifies all Principal Investigators holding any of the NIH research grants (listed below) that funds are available for administrative supplements to support and recruit students, postdoctorates, and eligible investigators. Administrative supplements must support work within the scope of the original project.

The NIH recognizes a unique and compelling need to promote diversity in the biomedical, behavioral, clinical and social sciences research workforce. The NIH expects efforts to diversify the workforce to lead to:

- the recruitment of the most talented researchers from all groups;
- an improvement in the quality of the educational and training environment;
- a balanced perspective in the determination of research priorities;
- an improved capacity to recruit subjects from diverse backgrounds into clinical research protocols;

- an improved capacity to address and eliminate health disparities.

Although the NIH currently provides multiple opportunities to develop research careers and improve participation for individuals from groups with low representation in the biomedical and behavioral sciences, reports from the National Science Foundation (NSF), (see <http://www.nsf.gov/sbe/srs/women/start.htm>) and others provide strong evidence that diversity remains an important problem that the entire research enterprise must actively address.

There is abundant evidence that the biomedical and educational enterprise will directly benefit from broader inclusion. Recent studies have supported the argument that diversity enhances the quality of education in multiple settings. Studies have suggested that racially and culturally concordant scientific staff may be more successful in recruiting individuals from minority groups into clinical trials. Racially similar physician-patient dyads also may be related to greater patient satisfaction in ways that could enhance communication and participation in clinical research settings. There is limited evidence that individuals who have participated in the NIH administrative supplement program preferentially conduct research in areas related to health disparities or minority health. There is no question that the need for a diverse workforce permeates all aspects of the nation's health-related research effort.

Accordingly, the NIH continues to encourage institutions to diversify their student and faculty populations and thus to increase the participation of individuals currently underrepresented in the biomedical, clinical, behavioral, and social sciences. This announcement describes programs designed to stimulate the participation of individuals from the following groups:

A. individuals from underrepresented racial and ethnic groups;

B. individuals with disabilities; and

C. individuals from socially, culturally, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research.

Although the administrative supplements supported under this program provide funding for less than one percent of all individuals involved in NIH supported research, the NIH has found these programs to be an effective means of encouraging institutions to recruit from currently underrepresented groups. Data on prior NIH administrative supplement programs are available at <http://grants.nih.gov/training/outcomes.htm>. All NIH awarding components participate in this program. This program is designed to provide support for research experiences for individuals from the identified groups throughout the continuum from high school to the faculty level. Continuation of this program in the future will be dependent on frequent evaluation of the career outcomes of the individuals who receive support as well as continuing assessments of the diversity of the scientific workforce as reported by the NSF and others.

## Section II. Award Information

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### 1. Mechanism(s) of Support

#### Eligible Awards:

Principal Investigators at domestic institutions who hold an active R01, R10, R18, R22, R24, R35, R37, R43, R44, R41, R42, P01, P20, P30, P40, P41, P50, P51, P60, U01, U10, U19, U41, U42, U54, or S06 grant may be eligible to submit a request for an administrative supplement to the awarding component of the parent grant. Because policies may vary among awarding components regarding eligibility of Small Grant Awards (R03), Academic Research Enhancement Awards (R15), or Exploratory/Developmental Grants (R21) for supplements under this program, **grantees holding those awards must check with the appropriate awarding component before submitting an application for a supplement**. Supplements to the R15, R03 and the R21 may provide support above the established dollar limits for the parent grant award. The P20, P30, and P60 award mechanisms are eligible for supplements only if they contain research components. The S06 award mechanism is only eligible for supplements to support postdoctoral fellows and faculty. In all cases, the mechanism of support under this program is the supplemental award.

At the time of a supplemental award, the parent grant must have support remaining for a reasonable period (usually two years or more). Applications may be submitted to support high school students, undergraduate students, post-baccalaureate students, post-master's degree students, graduate students, individuals in postdoctoral training, or faculty members who will participate in the ongoing research project. Specific eligibility requirements relative to each level of award are set forth in the description of the individual supplement programs (shown in [Section III.2.](#), below). This program also will provide additional support for established NIH investigators and project leaders on components of program projects and center grants who become disabled.

## 2. Funds Available

The NIH expects to make more than 1,000 administrative supplements under this program at a total cost exceeding \$60 million. Direct costs for individual administrative supplements vary from less than \$5,000 to more than \$75,000 depending on the career level of the candidate (see [Section III.3.](#), below). Requests for administrative supplements can be submitted to the NIH Program Official listed in the contacts section at any time. Administrative supplements normally end with the competitive cycle of the parent grant.

## Section III. Eligibility Information

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### 1. Eligible Applicants

#### 1.A. Eligible Institutions

Current NIH grant holders (as described above) may submit (an) application at any time.

#### 1.B. Eligible Individuals

For the purpose of this announcement, institutions are encouraged to identify candidates who will increase diversity on a national or institutional basis. The strength of an institution's description and justification for the appointment of an identified candidate will be judged along with all other aspects of the proposed experience (see review criteria in [Section V.1.](#)). As discussed, the NIH is particularly interested in encouraging the recruitment and retention of the following classes of candidates:

A. Individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in health-related sciences on a national basis (see <http://www.nsf.gov/sbe/srs/women/start.htm>). In addition, it is recognized that underrepresentation can vary from setting to setting and individuals from racial or ethnic groups that can be convincingly demonstrated to be underrepresented by the grantee institution are eligible for support under this program.

B. Individuals with disabilities, which are defined as those with a physical or mental impairment that substantially limits one or more major life activities.

C. Individuals from disadvantaged backgrounds which are defined as:

1. Individuals who come from a family with an annual income below established low-income thresholds. These thresholds are based on family size; published by the U.S. Bureau of the Census; adjusted annually for changes in the Consumer Price Index; and adjusted by the Secretary for use in all health professions programs. The Secretary periodically publishes these income levels at <http://aspe.hhs.gov/poverty/index.shtml>. For individuals from low income backgrounds, the institution must be able to demonstrate that such candidates have qualified for Federal disadvantaged assistance or they have received any of the following student loans: Health Professions Student Loans (HPSL), Loans for Disadvantaged Student Program, or they have received scholarships from the U.S. Department of Health and Human Services under the Scholarship for Individuals with Exceptional Financial Need.

2. Come from a social, cultural, or educational environment such as that found in certain rural or inner-city environments that have demonstrably and recently directly inhibited the individual from obtaining the knowledge, skills, and abilities necessary to develop and participate in a research career. Eligibility related to a disadvantaged background is most applicable to high school and perhaps to undergraduate candidates, but would be more difficult to justify for individuals beyond that level of academic achievement.

Awards under this program are limited to citizens or non-citizen nationals of the United States or to individuals who have been lawfully admitted for permanent residence in the United States (i.e., in possession of an Alien Registration Receipt Card or some other legal evidence of admission for permanent residence at the time of application).

Before submitting an application for a research supplement, applicants are strongly encouraged to contact their program administrator to discuss the program. NIH contacts for each awarding institute are listed under ?Inquiries? at the end of this document.

The NIH believes that by providing research opportunities for qualified individuals at various career levels, the number entering and remaining in health-related research careers will increase. Accordingly, Principal Investigators are encouraged to consider administrative supplements under this program for candidates at the following career levels:

- High School Students who have expressed an interest in the health-related sciences.
- Undergraduate Students who have demonstrated an interest in and wish to pursuing graduate level research training in health-related sciences.
- Post-Baccalaureate Students and Post-Master's Degree Students who have recently graduated and have demonstrated an interest and wish to pursue further graduate level training in health-related research sciences.
- Predoctoral Students who wish to develop their research capabilities in the health-related sciences.
- Individuals in Postdoctoral Training who wish to participate as postdoctoral researchers in ongoing research projects and career development experiences in preparation for an independent career in a health-related research.
- Faculty who wish to participate in ongoing research projects while further developing their own independent research potential.
- Established investigators who become disabled. This program will provide additional support for established NIH investigators and project leaders on components of program projects and center grants who become disabled. The additional support may be requested for assistance or special equipment that will facilitate a continuing contribution to the goals of the parent grant. Because this program differs in substantial ways from the other supplemental awards listed here, it is described in a separate section below.

Special Considerations related to each career level are discussed in Section III, Part 3, below.

## 2. Cost Sharing

Not applicable

## 3. Other-Special Eligibility Criteria

In all cases, the proposed research experience must be an integral part of the approved, ongoing research of the parent grant and it must have the potential to contribute significantly to the research career development of the candidate. Applications for supplements must include a plan for the candidate to interact with other individuals on the parent grant, to contribute intellectually to the research, and to enhance her/his research skills and knowledge regarding the selected area of biomedical science. It must also provide evidence of a focus on the enhancement of the research capability of the underrepresented or disadvantaged student or faculty member and that the research experience is intended to provide opportunities for development as a productive researcher. In addition, it must demonstrate that the Principal Investigator is willing to provide appropriate mentorship.

Usually, a parent grant may support only one individual on a supplement. However, investigators are encouraged to recruit more than one high school or undergraduate student for support by a supplemental award. Appointment of more than one individual to a single grant above the high school or undergraduate level depends on the nature of the parent grant, the circumstances of the request, and the program balance of the NIH awarding component. Candidates may receive support from only one supplement program at a time, but may be supported by more than one supplement during the development of their research careers. Support under the supplement program is not transferable to another individual or transportable to another institution.

These programs have been designed to attract individuals from underrepresented groups into research careers and are not intended to provide an alternative or additional means of supporting individuals who already receive support from an NIH research grant, an NIH National Research Service Award (NRSA), or any other DHHS funding mechanism. Graduate students or individuals in postdoctoral training who are supported by an Institutional NRSA may not be transferred to supplemental support prior to the completion of their appointed period of training. Individuals may not be transferred to a supplement to increase the availability of funds to the parent grant for other uses.

Applicants are strongly encouraged to contact the NIH institute staff prior to submission to obtain specific information about eligibility and preparing and submitting an application.

In addition to eligibility provisions discussed in the general procedures, there are special considerations associated with different career levels. The following describes special requirements for High School Students; Undergraduate Students; Post-Master's and Post-Baccalaureate Degree Students; Graduate Students; Postdoctoral Researchers; Faculty Level Researchers, and Individuals who Become Disabled.

**High School Students:** The purpose of this program is to provide high school students with an opportunity to obtain a meaningful experience in various aspects of health-related research to stimulate their interest in careers in biomedical, behavioral, clinical or social sciences. Any eligible high school student who is currently enrolled and in good standing at her or his high school and is interested in biomedical, behavioral, clinical or social research is encouraged to participate in this program.

**Undergraduate Students:** This supplement program provides an opportunity for undergraduate students interested in health-related research to participate in a research project during the summer months and/or during the academic school year. This experience is separate from any requirement of the regular academic program. The student may be affiliated with either the applicant institution or another academic institution. Any eligible undergraduate student interested in health-related research is encouraged to participate in this program.

**Post-Baccalaureate And Post-Master's Degree Students:** This supplement will provide opportunities for recent baccalaureate or master's degree graduates who wish to spend up to two years engaged in health-related research while applying for admission to graduate or medical school. The duration of the program is normally one year, but the research experience can be extended for an additional year if evidence is provided to show that the candidate is actively pursuing entry into a graduate or a health professions school. This program may not be used to provide technical support to NIH-supported investigators. Recent graduates who have earned either a bachelor's or master's degree in a health-related science are eligible for consideration. Students who plan to attend medical, dental or other professional schools are encouraged to use this program to gain research experience.

**Graduate Research Assistants:** The objective of this program is to reach out to graduate students already in biomedical, behavioral, clinical or social sciences and provide an opportunity to further develop their research capabilities. However, students who are currently supported on research or training grants may not be supported on research supplements. Any eligible graduate student who is enrolled in a master's or a research doctoral degree program in biomedical, behavioral, clinical or social sciences is eligible for consideration. Students in medical school or other professional schools are encouraged to use this program to gain research experience. Students in Ph.D. degree programs who are supported on supplements are encouraged to apply for the Ruth L. Kirschstein National Research Service Award, or similar types of support (e.g. dissertation grants) from the NIH, other federal agencies, or private organization.

**Individuals in Postdoctoral Training:** These supplements provide research support to permit individuals in the postdoctoral phase of their training to participate in ongoing research projects. This experience must serve as a means of assisting the postdoctoral fellow's development into productive researcher in a health-related science. Postdoctoral fellows who are currently being supported on research or training grants may not be supported on research supplements. Supported candidates should be encouraged to submit applications for fellowships, research grants, and other sources of independent support before the supplement period ends. The individual in postdoctoral training may be affiliated with either the applicant institution or some other institution. Only under extraordinary circumstances, which must be well justified in the application, would it be acceptable for the postdoctoral candidate to work with his/her former predoctoral mentor.

**Investigators Developing Independent Research Careers:** These supplements provide either short or long-term research support for faculty members to enhance their research skills and establish an independent research career.

**Short-term Investigator Research Supplement:** This supplement provides short-term support for faculty members to conduct full-time research for three to five months each year during the summer or another portion of the academic year, over a maximum period of four years.

**Long-term Investigator Research Supplement:** This supplement provides long-term research support for faculty members to conduct research in the biomedical or behavioral sciences. Support is usually provided for up to two years at a minimum of 75 percent effort during each 12-month period.

In both cases, the investigator may be affiliated with the applicant institution or some other institution. The investigator must have a doctoral degree, be beyond the level of a research trainee, typically employed at the junior faculty level (instructor or assistant professor) with at least one year of postdoctoral or equivalent research experience. The candidate is still eligible if they have previously received support from these programs: the Minority Biomedical Research Support (MBRS) Program, Minority-Research Infrastructure Support Program (M-RISP), the Minority Access to Research Career (MARC) Program, Career Opportunities in Research Education and Training (COR), Small Grants (R03), National Research Service Award (NRSA) predoctoral (F31) and postdoctoral (F32) fellowships, or the Academic Research Enhancement Award (AREA) Program (R15). On the other hand, an individual who has received previous funding from NIH as an independent Principal Investigator on a regular research grant (e.g., R01, R29), or as the project leader on a component of a program project or center grant (e.g., P01, P50, G12), or as Principal Investigator on an individual research career award (e.g., KO1, K02, K07, K08, and K12) is not eligible.

**Supplements for Established Investigators Who Become Disabled:** Established investigators on NIH research, program project, or center grants who become disabled during the current project period may request funds for reasonable accommodations to permit completion of the currently funded research project. Any currently funded Principal Investigator or Co-Investigator (hereinafter referred to as Established Investigator) on an NIH research project grant, program project grant, or center grant may request support for special equipment, an assistant, or other modifications to facilitate reasonable accommodation to a disabling injury or illness that has occurred during the current project period.



## Section IV. Application and Submission Information

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### 1. Address to Request Application Information

The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).

Telecommunications for the hearing impaired: TTY 301-451-0088.

### 2. Content and Form of Application Submission

Applications must be prepared using the PHS 398 research grant application forms (rev. 9/2004). Applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dnb.com>. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

See [Section VI.2 Award Administration](#) Information. for additional information.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

A request for a supplement may be submitted at any time. In making requests, the grantee institution, on behalf of the Principal Investigator of the parent grant and in cooperation with the candidate **must submit the request for supplemental funds directly to the awarding component that supports the parent grant. The request should not be submitted to the NIH Center for Scientific Review.** The Principal Investigator must submit one original and two copies of the application to the address listed under the appropriate awarding component under Agency Contacts in [Section VII.1.](#), of this document.

The request for a supplemental award must include the following:

- A completed face page (with appropriate signatures) from Grant Application Form PHS 398. Include the title and grant number of the parent grant on line 1 and the name ?Research Supplements to Promote Diversity in Health-Related Research? on line 2.
- A brief three to four page description, prepared by the Principal Investigator of the parent grant that includes:
  - A summary or abstract of the funded grant or project.
  - A plan and timeline for the research and career development experiences proposed for the candidate.
  - A description of how the research and career development experiences will expand and foster the research capabilities of the candidate; how the proposed experiences relates to the specific research goals and objectives of the parent grant; and a description of the mentorship that will be provided.
- A signed statement from the candidate outlining her/his research objectives and career goals.
- A biographical sketch of the candidate that includes evidence of scientific achievement or interest. The source of current funding must also be listed.
- Social Security Number of the candidate. (The PHS uses the Social Security Number for the purpose of accurate identification, referral, and review of applications and for efficient management of PHS grant programs. Although provision of the Social Security Number is voluntary, it will facilitate the processing of applications for supplements.)
- A signed statement from the Principal Investigator and an institutional official establishing the eligibility of the candidate for support under this program. The statement must include clearly presented information on citizenship as well as the nature of the candidate's disability, circumstances, background, or characteristics that confer eligibility under this program (see eligibility classes listed in [Section III, Part 1.B.C.1](#)). Documentation of participation in programs described in [Section III, Part 1.B.C.1](#) must be provided for individuals from low income backgrounds. Similarly, there must be objective evidence related to a background in a socially, culturally, or educationally disadvantaged environment for those using the criteria in [Section III, Part 1.B.C.2](#). The statement must include a convincing description of how the appointment of this specific candidate will address the issue of diversity within the national scientific workforce or within the workforce or the relevant population at the grantee institution. Finally, the statement must additionally describe any current or previous PHS research grant support the candidate has received. The strength of this statement will be considered by the NIH administrative review committee along with all other material provided.
- A proposed budget entered on budget pages from Grant Application Form PHS 398, related to the percent effort (where appropriate) for the research experience of the candidate during the first and future years. If the initial budget period requested is less than 12 months, the budget must be prorated accordingly.



- Documentation, if applicable, that the proposed research experience was approved by the Institutional Animal Care and Use Committee (IACUC) or human subjects Institutional Review Board (IRB) at the grantee institution must be provided. Adherence to the NIH policy for including women and minorities in clinical studies must also be insured if additional human subjects' involvement is planned for the supplement component.
- A copy of the most recent official transcript if the candidate is a high school, undergraduate, post-baccalaureate degree, post-master's degree, or graduate student.
- If the candidate is a student at another institution during the academic year, the application must include an appropriately signed letter from a responsible official at the institution of matriculation indicating that participation at the stated level of effort is approved and will not detract from or interfere with the student's course of studies.
- If any of the research is to be conducted at a site other than the grantee institution, an appropriately signed letter from the institution where the research is to be conducted must be submitted. The request must be signed by the candidate, the Principal Investigator, and the appropriate institutional business official.
- If the request is for a supplement based on disability, the institution should indicate what, if any, reasonable accommodations the institution has supported or plans to provide along with a full description of how any additional support for accommodation might be used. The relationship of the proposed accommodation to the proposed project must be described.

### 3. Submission Dates

Applications must be mailed directly to the awarding component and may be mailed at any time.

#### 3.A. Receipt, Review and Anticipated Start Dates

Letter of Intent Receipt Date: Not required

Application Receipt Date(s): May be submitted at any time

Peer Review Date: Applications can be reviewed at any time

Council Review Date: Not applicable

Earliest Anticipated Start Date: Notification approximately 10 weeks after receipt

##### 3.A.1. Letter of Intent

A letter of intent is not required for the funding opportunity.

#### 3.B. Sending an Application to the NIH

A request for a supplement may be submitted at any time. In making requests, the grantee institution, on behalf of the Principal Investigator of the parent grant and in cooperation with the candidate **must submit the request for supplemental funds directly to the awarding component that supports the parent grant . The request should not be submitted to the NIH Center for Scientific Review.** The Principal Investigator must submit one original and two copies of the application to the address listed under the appropriate awarding component in the "Inquiries" section of this document.

#### 3.C. Application Processing

Applications are received and evaluated for completeness by NIH staff within the awarding component that supports the parent grant.

Although there may be no immediate acknowledgement of the receipt of an application, applicants are generally notified of the decision to fund the supplement within approximately ten weeks after receipt.

### 4. Intergovernmental Review

This initiative is not subject to [intergovernmental review](#).

### 5. Funding Restrictions

All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm> (See also [Section VI.3. Award Criteria](#))

Awards are based on the current programmatic needs of the NIH awarding component, therefore investigators must contact their program administrators at the NIH before applying. The decision to fund a supplement will take approximately ten weeks from receipt of a complete application

In competing renewal applications, funds for continuation of support of the supplemental award will depend on the successful renewal of the parent grant and will be handled as follows:

For students who have not yet completed their research experience, funds for the continuation of support must be requested as a research supplement to ensure continued tracking of the individual supported. The request for continued support should not be included in the competing renewal, but instead, should be prepared as a letter with information on research progress and accomplishments of the candidate. The request must be addressed to the program administrator of the parent grant and must be submitted promptly in anticipation of a renewal award to avoid an interruption of support. Support for individual students by the supplement mechanism will be limited to five years. Additional time may be considered, particularly for students and investigators who have disabilities, but must be well justified.

Funds for the continuation of support for a postdoctoral fellow or an investigator must be requested by name in the parent grant application at the time of renewal and may not be requested as a research supplement. Postdoctoral fellows and investigators are expected to be fully integrated in the research laboratory when considered for continuation of support.

Supplement awards must be consistent with the goal of strengthening the existing research program and with the overall programmatic balance and priorities of the funding component of the NIH. Awards will be made according to the policies and provisions stated in this announcement or as further specified by the NIH component funding the parent grant. The award limits listed in this document for each career level represent the support the NIH will provide. An award does not preclude the institution's use of funds from other sources to supplement the award.

Applicants for summer-only research appointments must submit early enough to ensure that funding is in place by the time the summer experience is scheduled to begin. In most cases, during the first budget period, funds will be provided as an administrative supplement to the parent grant. In subsequent years, continued funding for the supplement is contingent on continued funding of the parent grant and cannot extend beyond the current competitive segment of the parent grant and the availability of funds.

**Reasonable Accommodations :** As part of these awards, funds may be requested to make changes or adjustments in the research setting that will make it possible for qualified individual with a disability to perform the essential functions associated with his/her role on the project. The accommodations requested under this program must be DIRECTLY related to the performance of the proposed role on the research project and must be appropriate to the disabilities of the individual. Some types of accommodations that might be provided under these awards include: specialized equipment, assistive devices, and personnel such as readers, interpreters, or assistants. In all cases, the total funds for accommodations requested from the supplement must be reasonable in relationship to the direct costs of the parent grant and the nature of the supplement award.

**High School Students:** The salary for a high school student, whether full- or part-time, should be consistent with the institutional salary policies. Institutional salary rates for high school students which exceeds the hourly minimum wage must be justified. Equipment may not be purchased with these funds. Students are expected to devote sufficient effort to the research project and related activities during the period of support to gain insight into the process of scientific discovery. Support for at least three months is encouraged during any one year. This may include a mixture of full-time summer experience and part-time experience during the school year. Principal Investigators are encouraged to seek high school students who will devote at least two years to this program (i.e., equivalent to two three-month, full-time periods). Exceptions to the latter will be considered, depending on the circumstances of the applicant, the parent grant, and the specific request.

**Undergraduate Students:** The salary for an undergraduate student should be consistent with the institutional salary policies. Institutional rates for undergraduate salary that exceeds \$10 per hour must be justified. An additional amount of \$200 per month for supplies and travel may also be requested. Equipment may not be purchased using these funds. Students are expected to devote the equivalent of at least three months of full-time effort to the research project and related activities in any one year and, in most cases, the period of support for any individual should last at least two years. Exceptions to these requirements will be considered, depending on the circumstances of the applicant, the parent grant, and the specific request.

**Post-Baccalaureate And Post-Master's Degree Students:** The salary for students at the post-baccalaureate and post-master's degree levels should be reasonable and consistent with the institutional salary policies and can not exceed the amount allowed for graduate students. Additional funds up to \$3,000 per year may be requested for supplies and travel. Funds may not be used to purchase equipment.

**Graduate Research Assistants:** The NIH will provide salary support in addition to other necessary expenses, such as supplies and travel, to enable the individual to participate as a graduate research assistant in funded research project. The NIH will provide compensation that (1) conforms to the established, consistently applied salary and wage policies of the institution and

(2) reflects the percentage of time devoted to the PHS-funded project. For graduate students this compensation may include tuition remission paid as, or in lieu of, wages provided that the student is in a bona fide employer-employee relationship with the institution for the work performed, and payment is made explicitly for performance of necessary work. The total amount requested for salary, tuition and fringe benefits can not exceed the amount allowable for a first year postdoctoral fellow at the same institution performing comparable work (see NIH Guide announcement, <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html>). Additional funds up to \$4,000 per year may be requested for supplies and travel. Funds may not be used to purchase equipment.

**Individuals In Postdoctoral Training:** The NIH will provide support for salary in addition to other necessary expenses, such as travel and supplies, to enable the candidate to participate as a postdoctoral research assistant or associate on the funded research project. The requested salary and fringe benefits must be in accordance with the salary structure of the grantee institution, consistent with the level of effort, and may not exceed \$50,000 per year. However, exceptions to this rule may be made. Applicants must check with their program administrators at the NIH before submitting an application. The supplement budget may include up to \$6,000 for supplies and travel for the candidate. These funds may not be used to purchase equipment.

**Investigators Developing Independent Research Careers:** The requested salary and fringe benefits for an investigator should be consistent with the level of support provided by NIH Career Development Awards. When that is not appropriate, the requested salary and fringe benefits can be up to \$85,000 total direct cost. This includes the candidate's salary of up to \$75,000 per year plus fringe benefits, in accordance with the salary structure of the grantee institution, and must be consistent with the level of effort. Additional funds of up to \$10,000 may be requested for supplies and travel. Equipment may not be purchased except in unusual circumstances and not without prior approval of the NIH awarding component. The maximum period of support for any investigator is usually two years. Applicants must contact the NIH staff listed under Inquiries prior to submission to obtain specific information about preparing and submitting an application.

**Supplements for Established Investigators Who Become Disabled:** Support will be limited to items that will permit the investigator to complete the remaining years of a currently funded research project. This might include: salary support for an individual who can assist the Established Investigator in meeting the goals of the research project, specialized equipment such as computers, or modifications of the working environment. In all cases, the requested support must be consistent with the type of disability and the nature of the approved research. The total amount of support requested under this supplement must be reasonable in relationship to the direct costs of the parent award and the Established Investigator's role and effort on the project. In future competing applications, funds for continuation of the accommodations provided under this supplement must be requested in the parent grant application and may NOT be requested as a research supplement.

## 6. Other Submission Requirements

### Plan for Sharing Research Data

Normally, not applicable.

### Sharing Research Resources

Normally, not applicable.

## Section V. Application Review Information

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### 1. Criteria

The staff of the NIH awarding component will review requests for a supplement to determine its overall merit. The following general criteria will be used:

- The qualifications of the candidate including career goals, prior research training, research potential, and any relevant experience.
- Evidence of educational achievement and interest in science, if the candidate is a student.
- The strength of the description of how this particular appointment will promote diversity within the institution or in science nationally.
- The plan for the proposed research and career development experiences in the supplemental request and their relationship to the parent grant.
- Evidence that the proposed experience will enhance the research potential, knowledge, and/or skills of the candidate and that adequate mentorship will be provided.
- Evidence that the activities of the candidate will be an integral part of the project.

## 2. Review and Selection Process

Applications submitted for this funding opportunity will be assigned to the awarding component for the parent grant and will be reviewed using the criteria shown above.

## 3. Merit Review Criteria

Applications submitted in response to a funding opportunity will compete for available funds with all other recommended applications using the criteria shown in [Section V.1.](#), above.

### 3.A. Additional Review Criteria:

In addition to the above criteria, the following items will be applied only when it has not been previously reviewed as part of the parent grant:

- Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).
- Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398).
- Inclusion of Women Plan - for clinical research only. Does the applicant propose a plan for the inclusion of both genders that will provide their appropriate representation? Does the applicant provide appropriate justification when representation is limited or absent? Does the applicant propose appropriate and acceptable plans for recruitment/outreach and retention of study participants?
- Inclusion of Minorities Plan - for clinical research only. Does the applicant propose a plan for the inclusion of minorities that will provide their appropriate representation? Does the applicant provide appropriate justification when representation is limited or absent? Does the applicant propose appropriate and acceptable plans for recruitment/outreach and retention of study participants?
- Inclusion of Children Plan- for all studies involving human subjects. Does the applicant describe an acceptable plan in which the representation of children of all ages (under the age of 21) is scientifically appropriate and recruitment/retention is addressed realistically? If not, does the applicant provide an appropriate justification for their exclusion?
- Data and Safety Monitoring Plan ? for clinical trials only. Does the applicant describe a Data and Safety Monitoring Plan that defines the general structure of the monitoring entity and mechanisms for reporting Adverse Events to the NIH and the IRB?
- Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.
- Biohazards: Is the use of materials or procedures that are potentially hazardous to research personnel and/or the environment proposed? Is the proposed protection adequate?

### 3.B. Additional Review Considerations

Not applicable

### 3.C. Sharing Research Data

Not applicable

### 3.D. Sharing Research Resources

Not applicable

## Section VI. Award Administration Information

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### 1. Award Notices

Approximately ten weeks after receipt of the application, applicants will be notified of the intent to award. Staff at the awarding component will describe the award process at that time.

## 2. Administrative Requirements

Not applicable

### 2.A. Cooperative Agreement Terms and Conditions of Award

Not applicable

## 3. Award Criteria

Awards are based on the current programmatic needs of the NIH awarding component, therefore investigators must contact their program administrators at the NIH before applying. The decision to fund a supplement will take approximately ten weeks from receipt of a complete application.

## 4. Reporting

In non-competing continuation applications, the progress report and budget for the supplement must be clearly delineated from the progress report and budget for the parent grant. The progress report must include information about the research and career development activities supported by the supplement even if support for future years is not requested. Continuation of support for the candidate in the remaining years of the competitive segment of the grant will depend upon satisfactory review by the NIH awarding component of progress for both the parent grant and the supplement project, the research proposed for the next budget period, and the appropriateness of the proposed budget for the proposed effort. This information is submitted with the PHS Non-Competing Grant Progress Report, Form 2590, which can be found at <http://grants.nih.gov/grants/funding/2590/2590.htm> and financial statements as required in the NIH Grants Policy Statement. In the future, identifying information on candidates supported by supplements will be collected at the beginning of the supplement period and at the beginning of each award year in order to evaluate the impact of this program on the candidates career development.

## Section VII. Agency Contacts

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We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

### 1. Scientific/Research Contacts:

Principal Investigators interested in participating in these programs must contact NIH staff administering the parent grant. For general information about the ***Research Supplements to Promote Diversity in Health-Related Research***, contact the following staff person in the appropriate awarding component:?

#### **National Institute on Alcohol Abuse and Alcoholism**

Judith A. Arroyo, Ph.D.  
Division of Epidemiology and Prevention Research  
5635 Fishers Lane, Room 2084  
Bethesda, MD 20892-9304  
Telephone: (301) 402-0717  
FAX: (301) 443-8614  
E-mail: [judith.arroyo@nih.hhs.gov](mailto:judith.arroyo@nih.hhs.gov)  
Web site: <http://www.niaaa.nih.gov>

#### **National Institute on Aging**

Michael-David A.R.R. Kerns, M.B.A., M.S., Ph.D.  
Office of Extramural Affairs  
7201 Wisconsin Avenue, Suite 2C218  
Bethesda, MD 20892-9205  
Telephone: (301) 496-9322  
FAX: (301) 402-2945  
E-mail: [michael.kerns@nih.hhs.gov](mailto:michael.kerns@nih.hhs.gov)  
Web site: <http://www.nia.nih.gov>

**National Institute of Allergy and Infectious Diseases**

Milton J. Hernandez, Ph.D.  
Director, Office of Special Populations and Research Training  
6700-B Rockledge Drive, Room 2101  
Bethesda, MD 20892-7610  
Telephone: (301) 496-3775  
FAX: (301) 496-8729  
E-mail: [milton.hernandez@nih.hhs.gov](mailto:milton.hernandez@nih.hhs.gov)  
Web site: <http://www.niaid.nih.gov>

**National Institute of Arthritis and Musculoskeletal and Skin Diseases**

Charisee Lamar, Ph.D., M.P.H.  
Program Director,  
Multidisciplinary Centers and Diversity Programs  
One Democracy Plaza  
6701 Democracy Blvd, Suit 800  
Bethesda, MD 20892-4872  
Telephone: (301)594-5052  
FAX: (301)480-4543  
E-mail: [charisee.lamar@nih.hhs.gov](mailto:charisee.lamar@nih.hhs.gov)  
Web site: <http://www.nih.gov/niams/grants/ep10.htm>

**National Institute of Biomedical Imaging and Bioengineering**

Sandra T. Talley  
Program Officer  
Extramural Science Programs  
6707 Democracy Blvd, Suite 200  
Bethesda, MD 20892-5469  
Telephone: (301) 451-4790  
FAX: (301) 480-4973  
E-mail: [sandra.talley@nih.hhs.gov](mailto:sandra.talley@nih.hhs.gov)  
Web site: <http://www.nibib.nih.gov>

**National Cancer Institute**

Peter Ogunbiyi, D.V.M., Ph.D.  
Program Director  
Comprehensive Minority Biomedical Branch  
6116 Executive Blvd, Room 7028  
Bethesda, MD? 20892-8347  
Telephone: (301) 496-7344  
FAX: (301) 402-4551  
Email: [peter.ogunbiyi@nih.hhs.gov](mailto:peter.ogunbiyi@nih.hhs.gov)  
Web site: <http://minorityopportunities.nci.nih.gov>

**National Institute of Child Health and Human Development**

Ralph Nitkin, Ph.D.  
Director, Biological science and Career Development Program  
National Center for Medical Rehabilitation Research  
6100 Executive Blvd. Room 2A03  
Bethesda, MD 20892-7510  
Tel.: (301) 402-4206  
FAX: (301) 402-0832  
E-mail: [ralph.nitkin@nih.hhs.gov](mailto:ralph.nitkin@nih.hhs.gov)  
Web site: <http://www.nichd.nih.gov>

**National Institute on Deafness and Other Communication Disorders**

Judith A. Cooper, Ph.D.  
Director, Division of Scientific Programs  
Executive Plaza South, Room 400C  
6120 Executive Blvd  
Bethesda, MD 20892-7180  
Telephone: (301) 496-5061  
FAX: (301) 402-6251



E-mail: [judith.cooper@nih.hhs.gov](mailto:judith.cooper@nih.hhs.gov)  
Web site: <http://www.nidcd.nih.gov>

#### **National Institute of Dental and Craniofacial Research**

Lorrayne Jackson  
Extramural Research Analyst and Outreach Specialist  
Office of the Director  
Natcher Bldg., Room 4AS-25K  
45 Center Drive  
Bethesda, MD 20892-6401  
Telephone: (301) 594-2616  
FAX: (301) 480-8322  
E-mail: [lorrayne.jackson@nih.hhs.gov](mailto:lorrayne.jackson@nih.hhs.gov)  
Web site: <http://www.nidcr.nih.gov>

#### **National Institute of Diabetes and Digestive and Kidney Diseases**

Frances Ferguson, M.D.  
Associate Director for Minority Health and Research  
Office of Minority Health Research Coordination  
6707 Democracy Boulevard, Room 644  
Bethesda, MD 20892-5454  
Telephone: (301) 594-9652  
FAX: (301) 594-9358  
E-mail: [frances.ferguson@nih.hhs.gov](mailto:frances.ferguson@nih.hhs.gov)  
Web site: <http://www.niddk.nih.gov>

#### **National Institute on Drug Abuse**

Lula A. Beatty, Ph.D.  
Chief, Special Populations Office  
Office of the Director  
6001 Executive Blvd, Room 4216  
Bethesda, MD 20892-9567  
Telephone: (301) 443-0441  
FAX: (301)480-8179  
E-mail: [lula.beatty@nih.hhs.gov](mailto:lula.beatty@nih.hhs.gov)  
Web site: <http://www.nida.nih.gov>

#### **National Institute of Environmental Health Sciences**

Carol A. Shreffler, Ph.D.  
Program Administrator,  
Training and Career Development Programs  
Division of Extramural Research and Training  
P.O. Box 12233  
Research Triangle Park, NC 27709  
Telephone: (919) 541-1445  
FAX: (919) 541-5064  
E-mail: [carol.shreffler@nih.hhs.gov](mailto:carol.shreffler@nih.hhs.gov)  
Web site: <http://www.niehs.nih.gov/dert/training.htm>

#### **National Eye Institute**

Ralph J. Helmsen, Ph.D.  
Research Resources Officer  
5635 Fishers Lane, Suite 1300  
Bethesda, MD 20892-9300  
Telephone: (301) 451-2020  
FAX: (301) 402-0528  
E-mail: [ralph.helmsen@nih.hhs.gov](mailto:ralph.helmsen@nih.hhs.gov)  
Web site: <http://www.nei.nih.gov>

#### **National Institute of General Medical Sciences**

Anthony A. Ren<sup>髒</sup>Ph.D.  
Assistant Director, Referral and Liaison  
45 Center Drive, Room 2AN-18F  
Bethesda, MD 20892-6200

Telephone: (301) 594-3833  
FAX: (301) 402-0156  
E-mail: [anthony.rene@nih.hhs.gov](mailto:anthony.rene@nih.hhs.gov)  
Web site: <http://www.nigms.nih.gov>

#### **National Heart, Lung, and Blood Institute**

Helena O. Mishoe, Ph.D., M.P.H.  
Associate Director  
Office of Minority Health Affairs  
Two Rockledge Centre, Suite 8093  
6701 Rockledge Drive  
Bethesda, MD 20892-7913  
Telephone: (301) 451-5081  
FAX: (301) 480-0862  
E-mail: [helena.mishoe@nih.hhs.gov](mailto:helena.mishoe@nih.hhs.gov)  
Web site: <http://www.nhlbi.nih.gov/funding/training/guid-app.htm>

#### **National Human Genome Research Institute**

Bettie J. Graham, Ph.D.  
Program Director  
Division of Extramural Research  
Suite 4076  
5635 Fishers Lane  
Bethesda, MD 20892-9305  
Telephone: (301) 496-7531  
FAX: (301) 480-2770  
E-mail: [bettie.graham@nih.hhs.gov](mailto:bettie.graham@nih.hhs.gov)  
Web site: <http://www.nhgri.nih.gov>

#### **National Library of Medicine**

Valerie Florance, Ph.D.  
Deputy Director  
Rockledge 1, Suite 301  
6705 Rockledge Drive  
Bethesda, MD 20892-7968  
Telephone: (301) 496-4882  
FAX: (301) 402-2952  
E-mail: [Valerie.Florance@nih.hhs.gov](mailto:Valerie.Florance@nih.hhs.gov)  
Web site: <http://www.nlm.nih.gov/ep>

#### **National Institute of Mental Health**

Michael A. Sesma, Ph.D.  
Chief, Research Scientist Development Program  
Office for Special Populations  
6001 Executive Blvd, Suite 8125  
Bethesda, MD 20892-9659  
Telephone: (301) 443-2847  
FAX: (301) 443-8022  
E-mail: [michael.sesma@nih.hhs.gov](mailto:michael.sesma@nih.hhs.gov)  
Web site: <http://www.nimh.nih.gov>

#### **National Institute of Neurological Disorders and Stroke**

David A. Jett, Ph.D.  
Program Director for Minority Health and Research  
Office of Minority Health and Research  
6001 Executive Blvd, NSC, Suite 2149  
Bethesda, MD 20892-9535  
Rockville, MD 20852 (for Express/Courier Service)  
Telephone: (301) 496-6035  
FAX: (301) 594-5929  
E-mail: [david.jett@nih.hhs.gov](mailto:david.jett@nih.hhs.gov)  
Web site: <http://www.ninds.nih.gov>

**National Institute of Nursing Research**

Genevieve deAlmeida-Morris, M.A., M.P.H.  
Acting Chief, Office of Science Policy and Public Liaison  
Building 31, Room 5B10  
Bethesda, MD 20892-6300  
Telephone: (301) 496-0207  
FAX: (301) 480-8845  
E-mail: [genevieve.dealmeida-moriss@nih.hhs.gov](mailto:genevieve.dealmeida-moriss@nih.hhs.gov)  
Web site: <http://ninr.nih.gov/ninr/>

**National Center for Research Resources**

Abraham Levy, Ph.D.  
Health Scientist Administrator  
Division of Biomedical Technology Research and Research Resources  
6701 Democracy Blvd, Room 970  
Bethesda, MD 20892-4874  
Telephone: (301) 435-0777  
FAX: (301) 480-3659  
E-mail: [abraham.levy@nih.hhs.gov](mailto:abraham.levy@nih.hhs.gov)  
Web site: <http://www.ncrr.nih.gov>

**Fogarty International Center**

Barbara J. Sina, Ph.D.  
MIRT Program Officer  
Division of Training and Research  
31 Center Drive, Room B2C39  
Bethesda, MD 20892-2220  
Telephone: (301) 402-9467  
FAX: (301) 402-0779  
E-mail: [barbara.sina@nih.hhs.gov](mailto:barbara.sina@nih.hhs.gov)  
Web site: <http://www.fic.nih.gov>

**National Center for Complementary and Alternative Medicine**

Morgan N. Jackson, M.D., M.P.H.  
Director, Office of Special Populations  
Division of Extramural Research and Training  
6707 Democracy Blvd., Suite 401  
Bethesda, MD 20892-5475  
Telephone: (301) 402-1278  
FAX: (301) 480-3621  
E-mail: [morgan.jackson@nih.hhs.gov](mailto:morgan.jackson@nih.hhs.gov)  
Web site: <http://nccam.nih.gov>

**National Center on Minority Health and Health Disparities**

DeLoris L-James Hunter, Ph.D. (CAPT)  
Director, Division of Research and Training Activities  
6707 Democracy Blvd, Suite 800  
Bethesda, MD 20892-5465  
Telephone: (301)402-1366  
FAX: (301)480-4049  
E-mail: [deloris.hunter@hhs.nih.gov](mailto:deloris.hunter@hhs.nih.gov)  
Web site: <http://www.ncmhd.nih.gov>

**2. Peer Review Contacts:**

Not applicable

**3. Financial or Grants Management Contacts:**

Not applicable

**Section VIII. Other Information**

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## Required Federal Citations

Choose all citations that are appropriate to the funding opportunity announcement.

### Use of Animals in Research:

Recipients of PHS support for activated involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>), as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>), as applicable.

### Human Subjects Protection:

Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained, <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.

### Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity, and dose-finding studies (phase I); efficacy studies (Phase II) efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

### Sharing Research Data:

Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible, [http://grants.nih.gov/grants/policy/data\\_sharing](http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies, local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

### Sharing of Model Organisms:

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement [http://grants.nih.gov/grants/policy/nihgps\\_2003/index.htm](http://grants.nih.gov/grants/policy/nihgps_2003/index.htm)). All investigators submitting an NIH application or contract proposal beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

### Inclusion of Women And Minorities in Clinical Research:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

### Inclusion of Children as Participants in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at <http://grants.nih.gov/grants/funding/children/children.htm>.

#### **Required Education on The Protection of Human Subject Participants:**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

#### **Human Embryonic Stem Cells (hESC):**

Criteria for federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see <http://escr.nih.gov/>). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

#### **Public Access to Research Data through the Freedom of Information Act:**

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at [http://grants.nih.gov/grants/policy/a110/a110\\_guidance\\_dec1999.htm](http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm). Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

#### **Standards for Privacy of Individually Identifiable Health Information:**

The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR web site (<http://www.hhs.gov/ocr>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

#### **URLs in NIH Grant Applications or Appendices:**

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

#### **Healthy People 2010:**

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

#### **Authority and Regulations:**

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of sections 301, 510, 515, and 504 of the Public Health Service Act. Federal regulations at 42 CFR Part 52, "Grants for Research Projects" and 45 CFR part 74, "Administration of Grants," are applicable to these awards. Grants must be administered in accordance with the NIH Grants Policy Statement (10/98). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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